## REMARKS

Claims 1-4 and 6-16 are pending in the present application, although claims 9-16 have been withdrawn from consideration. Claims 1-4 and 6-8 are now presented for reconsideration.

Claims 1-4 and 6 are rejected under 35 U.S.C. § 103(a) over International Publication No. WO 97/27898 to Evard, *et al.* ("Evard") in view of U.S. Patent No. 5,246,445 to Yachia, *et al.* ("Yachia"). Claims 7 and 8 are rejected under 35 U.S.C. § 103(a) over Evard in view of Yachia and in further view of U.S. Patent No. 5,645,559 to Hachtman *et al.* ("Hachtman") as applied to claim 1. Claims 1-3 are rejected under 35 U.S.C. § 103(a) over Evard in view of U.S. Patent No. 6,494,908 to Huxel *et al.* ("Huxel").

Applicants respectfully traverse these rejections and request reconsideration of the claims in light of the following remarks. Each of the outstanding rejections is addressed in the order in which it appears in the Office action.

### *Specification*

The Office action objects to the specification. Pursuant to MPEP § 608.01(o), Applicants hereby amend paragraph **[0009]** to provide clear antecedent basis for claim 1. Support for the amendment to the specification is found throughout the specification as filed and at least in paragraphs **[0009]** and **[0041]**.

### *Rejection under 35 U.S.C. § 103(a)*

Rejection of claims 1-4 and 6 over Evard in view of Yachia

Applicants respectfully submit that a prima facie case of obviousness has not been established with respect to independent claim 1. Independent claim 1 recites, in part, a stent comprising a coil segment, "wherein the spaced windings are separated by a distance in the range of from about 4 millimeters to about 10 millimeters." The Office action acknowledges that

Evard does not disclose separation of the windings within the range of 4 mm to 10 mm (see, the Office action at page 3, lines 3-5). Indeed, Applicants submit that nothing in Evard teaches or suggests a stent with windings that are separated by a distance in the range of from about 4 millimeters to about 10 millimeters. Yachia fails to remedy the deficiencies of Evard and, in fact, teaches away from Applicants claimed stent with windings that are separated by a distance in the range of from about 4 millimeters to about 10 millimeters.

Briefly, Yachia discloses a device "wound helically and tightly of thin wire." (Yachia column 4, lines 12-14, emphasis added). According to Yachia, "[i]t is important that the winding be sufficiently tight that the outer surface of the device is substantially continuous, thus preventing "leaking through" of the inner lining of a vessel or duct. However, in cases in which incorporation of the stent into the wall of a duct is preferred, space of about 0.1 to 2.0 mm will be left between the loops of the coil." (Yachia, column 4, lines 49-52, emphasis added).

As stated in MPEP § 2144.05, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. Claim 1 recites spaced windings "separated by a distance in the range of from about 4 millimeters to about 10 millimeters," a distance that fails to overlap or lie inside the space disclosed in Yachia, *i.e.*, about 0.1 to 2.0 mm. (See, Yachia column 4, lines 50-51).

The Office action, at page 3, asserts that

> [T]he prior art recitation of *about* 2mm for the spacings between windings in Yachia can be considered to be about 4mm since the use of "about" is broad and the interpretation can reasonably include a variance of ± 2mm. See MPEP 2144.05.

However, contrary to the Office action assertion, MPEP § 2144.05 clarifies, by example, the interpretation that "about 1-5%" allows for concentrations slightly above 5%, specifically, that

"about 5%" and slightly above 5% overlap. (Emphasis added). In this case, the claimed 4 millimeter distance between spaced windings is not slightly above 2 mm, rather, 4 mm is two times the amount of the largest space disclosed in Yachia. Yachia fails to disclose a range that overlaps with the claimed range of from about 4 millimeters to about 10 millimeters. Accordingly, the combination of Evard in view of Yachia fails to establish a *prima facie* case of obviousness.

Yachia fails to teach, suggest, or motivate increasing the space between the loops of the coil to fall within the claimed range. Rather, in contrast, Yachia emphasizes that the space between the loops of the stent coil should be small to provide tight windings. Specifically, Yachia discloses that "[i]t is important that the winding be sufficiently tight that the outer surface of the device is substantially continuous, thus preventing "leaking through" of the inner lining of a vessel or duct." (Yachia, column 4, lines 45-49, emphasis added). Yachia fails to motivate or suggest, and, in fact, teaches away from, increasing the spaced windings between the loops of the coil such that they fall in the range of from about 4 millimeters to about 10 millimeters.

A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. MPEP § 2141.02. Yachia explains that "[i]t is important that the winding be sufficiently tight" however, in certain cases, specifically, "in cases in which incorporation of the stent into the wall of a duct is preferred, space of about 0.1 to 2.0 mm will be left between the loops of the coil." (Yachia, column 4, lines 49-52, emphasis added). When viewed as a whole, Yachia emphasizes the importance of a tightly wound device and teaches away from expanding the about 0.1 to 2.0 mm space between the windings to a greater spacing.

As noted in MPEP § 2143.01, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. The Office action's proposed modification of Yachia would render the reference insufficient for its purpose. Specifically, modifying the distance between spaced windings in Yachia to a greater spacing than disclosed in Yachia would render Yachia's stent inoperable for its intended purpose, which is to have a sufficiently tightly wound device with an outer surface that is substantially continuous to prevent "leaking through" of the inner lining of a vessel or duct. (Yachia, column 4, lines 45-49).

For at least these reasons, Applicants submit that amended independent claim 1 is patentable over Evard in view of Yachia. Because claims 2-4 and 6 depend, either directly or indirectly, from independent claim 1, these claims are also patentable over Evard in view of Yachia.

Rejection of claims 7 and 8 over Evard in view of Yachia and in further view of Hachtman

Applicants respectfully submit that Hachtman fails to cure the deficiencies of Evard and Yachia with respect to independent claim 1. At a minimum, Hachtman does not teach or suggest a stent comprising a coil segment "wherein the spaced windings are separated by a distance in the range of from about 4 millimeters to about 10 millimeters." Hachtman is a mesh stent and does not have any windings.

Because claims 7 and 8 depend, either directly or indirectly, from independent claim 1, and include all the limitations thereof, Applicants submit that claims 7 and 8 are also patentable over Evard in view Yachia in further view of Hachtman.

Rejection of claims 1-3 over Evard in view of Huxel

Applicants respectfully submit that Huxel fails to cure the deficiencies of Evard with respect to independent claim 1. Huxel at least does not teach or suggest a stent comprising a coil segment "wherein the spaced windings are separated by a distance in the range of from about 4 millimeters to about 10 millimeters." Huxel does not disclose any range of spacing between windings.

The Office action, at page 5, asserts that Huxel "teaches a stent for body lumens can have a distance between coils of 4mm, col. 5, lines 47-51." Huxel discloses, at column 5, lines 47-55, that

> The pitch of the stent is defined to be the number of coils per unit length. In this patent application specification, for this example, pitch is defined as the number of coils per centimeter of stent length. Typically, for urethral applications, the pitch will be about 2.5 to about 100, more typically about 3 to about 20, and preferably about 5 to about 10. Although it is preferred for urethral applications that there be no space between adjacent coils, the stents of the present invention may have spaces between adjacent coils.

Huxel merely discloses the number of coils per centimeter of stent length and that there may be spaces between adjacent coils, "although it is preferred for urethral applications that there be no space between adjacent coils." Huxel does disclose that "the diameter for the urethral applications will be about 0.1 mm to about 4 mm." Column 5, lines 38-39 (emphasis added).

Accordingly, neither Evard nor Huxel, alone or in proper combination, teaches or suggests a stent comprising a coil segment "wherein the spaced windings are separated by a distance in the range of from about 4 millimeters to about 10 millimeters." Therefore, Applicants submit that independent claim 1 is patentable over Evard and Huxel. Because claims 2 and 3 depend, either directly or indirectly, from claim 1, these claims are patentable as well.

## CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration, withdrawal of all grounds of rejection, and allowance of claims 1-4 and 6-8 in due course. The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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